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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,905	01/21/2004	John N. Feder	D0297 NP	4411

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	**PAPER NUMBER**
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,905	FEDER ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-26* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 9-16* is/are withdrawn from consideration.

5)☒ Claim(s) *2,3,7,8,17 and 18* is/are allowed.

6)☒ Claim(s) *19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

1. Amendment after non-final filed 11/16/2006 is acknowledged.

2. Applicant's amendment and arguments filed 11/16/2006 have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).

3. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

4. Claims 2-26 are present in this application.

5. **Claims withdrawn**:

Claims 4-6 & 9-16 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Claims 2-3, 7-8 & 17-26 are under consideration in this examination.

7. **New Matter added to claims only** - [New Matter rejection]

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), **at the time the application was filed**, had possession of the claimed invention. Applicant's addition [new matter] of 'stringent hybridization conditions comprising an incubation period (??) at 37 degrees C in a hybridization conditions between 30% and 50% is not supported by the original disclosure. Paragraph 0050 of the published application defines 'stringent conditions at 42 degrees C and 50% formamide and the use of other buffers..'. No where is the

combination of '37 degrees C in a hybridization conditions between 30% and 50% formamide described to be high stringency conditions. Further **range** between 30% and 50% formamide is not taught. Applicants are required to cancel the new matter in reply to this office action.

The recitation of "nucleic acid fragment that hybridizes to SEQ ID NO: 1 or to selected nucleotides in claims 23 and 26" does not have support in the specification as filed. Applicants are required to cancel the new matter in reply to this office action.

8. ***Claim Rejections - 35 USC § 112*** (first paragraph)

Enablement

Claims 23 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of SEQ ID NO: 1 encoding a monoacylglycerol acyltransferase-3 (MGAT3) of SEQ ID NO: 2, does not reasonably provide enablement for all fragments of undetermined lengths, variants or allelic variants of SEQ ID NO: 1, or polynucleotides that can hybridize under specifically defined stringency conditions (high stringency conditions, for example) to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988))[*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the

predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary].

The claims are drawn to encompass all fragments of undermined lengths, variants or allelic variants of SEQ ID NO: 1, or polynucleotides that can hybridize under specifically defined stringency conditions (high stringency conditions, for example) to SEQ ID NO: 1. The specification, however, only discloses the full length sequence of a polynucleotide of SEQ ID NO: 1 encoding a monoacylglycerol acyltransferase-3 (MGAT3) of SEQ ID NO: 2. There is no disclosure or description of polynucleotide fragments, variants or allelic variants of SEQ ID NO: 1, or polynucleotides that can hybridize under specifically defined stringency conditions.

With regard to claim 23 & 26, directed to a polynucleotide sequence that hybridizes to the disclosed sequences, Applicants have not sufficiently defined the conditions under which the hybridizations are to take place. The conditions defined in the claims are not 'high stringency conditions'. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without a clear and explicit recitation of the conditions associated with the

hybridization. For example, the definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of the conditions which were actually used by Applicants in isolating the claimed polynucleotides which hybridize to the disclosed sequences, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. Including in the claims the exact nature of the hybridization conditions used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection. The rejection is maintained for lack of sufficient and appropriate hybridization conditions.

9. Claims 23 & 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of polynucleotide molecules with either SEQ ID NO: 1 or DNA having the limitations of encoding a protein, a fragment thereof, a variant thereof, or which can hybridize under undefined condition, which may be stringent and not specifically defined.

The specification does not contain any disclosure of the ***function*** of all the polynucleotide sequences that are fragments of SEQ ID NO: 1. The genus of polynucleotides that comprise these molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many

functionally unrelated polynucleotide are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

10. Applicants argue that the newly amended claims appear to resolve 112 enablement and/or written description rejections. This is not the case and is explained in the 112 enablement and/or written description rejections.

11. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 24-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-25, line 1, recite 'further comprising nucleotides 171-1190 or 168-1190...', is confusing because the claims depend upon claim 17 which recite SEQ ID NO: 1. This would mean apart from SEQ ID NO: 1 nucleotide residues 171-1190 or 168-1190 are present which are already present in SEQ ID NO: 1. Deleting the word 'further' is suggested to overcome this rejection.

12. **35 U.S.C. § 101**

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 19-22 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending claim 19 to recite wording such as "An isolated polynucleotide encoding *the* polypeptide of SEQ ID NO: 2". Claims 20-22 are included in the rejection for failing to correct the defect present in the base claim(s).

13. The declaration of Thomas Nelson filed on 11/16/2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gimeno et al. [US 20030170691 A1 or US 20060183210] reference because:

(1) Applicants US 20030170691 A1 claims priority to US Provisional 60/341,947 filed **12/19/2001**. Applicants have not sworn behind this priority date. The affidavit is not signed by all the inventors, as not all the pending claims are drawn to the elected invention.

(2) US 20060183210 is a division of US 20030170691 which also claims priority to US Provisional 60/341,947 filed **12/19/2001,** is now prior art under 102(e) and not abandoned. hence the 102(e) rejection is maintained and is repeated in hear.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the

> invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Gimeno et al. [US 20030170691 A1 or US 20060183210]. Gimeno et al. teach a polynucleotide sequence (SEQ ID NO: 7) which is about 87% identical to Applicants' SEQ ID NO: 1 and encodes a human diacylglycerol acyltransferase 2 (DGAT2). Gimeno's SEQ ID NO: 8, which is DGAT2 (protein), is **100%** identical to Applicants' protein of SEQ ID NO: 2, having MGAT activity. Gimeno et al. also teach vector, host cell and recombinant method of making the protein. Gimeno et al. teaching all the claim limitations is therefore anticipatory. (*See* the sequence search alignment between Applicants' SEQ ID NO: 1 & 2 and SEQ ID NO: 7 & 8, respectively, previous provided). Specific nucleotides of SEQ ID NO: 1 (i.e. nucleotides 171-1190 or 168-1190) are also taught.

Applicants' newly added claims to a polynucleotide encoding SEQ ID NO: 2, or such a polynucleotide being contained in a deposit or specific nucleotides of SEQ ID NO: 1 or wherein the polynucleotide hybridizes under stringent conditions would also be anticipated in view of high homology of the polynucleotide sequence of the prior art to SEQ ID N: 1 as well 100% homology to the SEQ ID NO: 2.

15. Claims 2-3, 7-8 & 17-18 are allowed because prior art of Gimeno et al. teaches a polynucleotide which is about 87% identical to Applicants' SEQ ID NO: 1 and therefore does not anticipate or make obvious SEQ ID NO: 1.

16. Claims 2-26 are pending in this application.

Claims 4-6 & 9-16 are withdrawn.

Claims 19-26 are rejected.

Claims 2-3, 7-8 & 17-18 are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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